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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,269	04/08/2004	Torsten Schulz	15111.0081	8565

27890 7590 04/23/2007

STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
OWENS, GARRISON A	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,269	SCHULZ ET AL.	
	Examiner	Art Unit	
	Garrison Owens	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-24,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restriction

Remarks

Applicant's election of Group I in the reply filed on 15 September 2006, and elected monocrystalline silicon as the base element (see claim 3), Borofloat 33 as the lid element (see claim 4); polydimethyl siloxane as the intermediate element (see claim 6); a protein library (see claim 18) and specifically an antibody library (as in claim 19) in the reply filed 04 January 2007, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03 (a))

Claim 25-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 September 2006 and 04 January 2007.

The Examiner hereby withdraws the requirement for election of species for the library of claim 18 and the antibody library of claim 19.

Claims 1-24, 44-45, are under examination.

Claims Rejections – 35 U.S.C. 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24, 44-45 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For **claims 1 and 44**, the term "fixable" is not clearly defined in the claims or specification of the reviewed application. Webster's dictionary defines the term as: "to make firm, stable, or stationary; to give a permanent or final form; to set or place definitely; to repair or mend; to change into a stable compound or available form." The term has multiple meanings and it is not clear to the examiner which definition the applicant intended to apply to the term. In this review, the claims will be treated as if the definition means, "to set, or place definitely", thus the current application will be analyzed for patentability with respect to that definition. However, this treatment does not relieve applicant of the burden of responding to the rejection. Therefore, the independent claims 1 and 44 and all dependent claims are rejected under 35 USC § 112, second paragraph.

For **claims 8, 10 and 16**, the term "may be" is vague and indefinite. The examiner is unclear for example in claim 8, if the chamber space is filled free of air bubbles or not. In claim 10, it is unclear if the chamber is cooled or not. And finally, in claim 16, it is not clear to the examiner if the device is operated fully automatically or not. For examination purposes, in this review, the claims will be treated as if the chamber space of claim 8 is filled free of air bubbles, and that the chamber of claim 10 is cooled. Finally, in this review, the claims will be treated as if the device of claim 16 is

operated fully automatically through a connector. However, this treatment does not relieve applicant of the burden of responding to the rejection.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. **Claims 1, 7** are rejected under 35 USC 102(b) as being anticipated by Dolan et al. (US Patent No. 6,136,182. Date of Patent is October 24, 2000).

For **claim 1**, Dolan et al., (see entire document) disclose a device (e.g., see figure 5; see also abstract, "An apparatus [i.e., a device] for observation of magnetically labeled cells..."). The device could be used for holding a substance library carrier (e.g., see figure 5, wherein element 14 is the carrier and the 11 members on the surface of the carrier denoted by the number 20 represent a site where a library could be bound. Note that the limitation "for holding a substance library carrier" represents "intended

use" and is not afforded patentable weight (e.g., see In re Danly, 263 F.2d844, 847, 120 USPQ 28,531(CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Baush & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP 2114). Dolan also disclose two holding elements that are fixable with each other (e.g., see figure 5b wherein the "two sides" of element 12 resent "holding elements" and they are "fixed at a distance that is equal to the length of element 14). Dolan et al. further disclose that the two fixable holding elements also form a layer composite comprising: (i) a lid element having a detection surface with a substance library on it's underneath side and being optically translucent at least in an area of the detection surface (e.g. see figure 1, element 14; see also column 12, lines 28-45, The wall member 14 is formed of a non-magnetic transparent material, such as glass, quartz, or clear plastic. Dolan et al. further disclose said composite comprises a sealing intermediate element having an enclosed recess (e.g., see figure 5a wherein "groove" along top of walls represents a "sealing intermediate element that has an "enclosed recess" when the top plate (i.e. element 14) is added to it). Dolan et al. disclose a base element being optically translucent at least in an area of the detection surface of the lid element (e.g., see figure 5, bottom portion of element 20). Finally, Dolan et al disclose that the lid element, the intermediate element and the base element together form an optically translucent chamber having a chamber space (e.g., see figure 5b).

For **claim 7,** Dolan, et al., discloses in column 12, lines 35-41, a vessel comprises a tub-shaped carrier member having a recess formed therein, and a top wall

member. The tub shaped carrier meets the claim limitation of "a geometric form". The top wall member is configured to fit into the carrier member to define a chamber bounded by the interior surface of the wall member. Furthermore, in the abstract, Dolan et al., also teaches the device consists of a chamber body with a recess whose edge sealingly holds an optically transparent chip.

Dolan et al., teaches every element of claims 1 and 7; therefore, these claims are rejected under 35 USC § 102b.

Claims 1-4, 7-8, 10, 12, 18-24, are rejected under 35 USC 102e as being anticipated by Ehricht et al., US 2002/0150933 (17 October 2002).

For **claim 1**, Ehricht et al., (see entire document including column 4, paragraph 55-58, and column 5, paragraphs 61-62) disclose a device (see Figure 1) for duplicating and characterizing nucleic acids, consists of a chamber body and a chamber support. Ehricht et al., also disclose a device for holding a chip (e.g. a nucleic acid chip or substance library see column 4, paragraph 55). As discussed previously, the Examiner contends that the limitation "for holding a substance library carrier" represents "intended use" and is not afforded patentable weight (e.g., see In re Danly, 263 F.2d844, 847, 120 USPQ 28,531(CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Baush & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP 2114).

Ehricht also discloses two holding elements that are fixable with each other (for example, see figure 1 wherein the "two sides" of element 42 represent "holding elements" and they are "fixed" at a distance that is equal to the length of element 2.

Ehricht also discloses that the two fixable holding elements also form a layer composite comprising: (1) a lid element having a detection surface with a library on its underneath side (that is positioned opposite and facing the surface of the chamber support see Figure 1 and also column 4, paragraph 55) and is optically translucent ate least in an area of the detection surface (see column 4, paragraphs 56 and 58). Ehricht et al., further disclose a sealing intermediate having an enclosed recess (column 3 paragraph 24; column 4, paragraph 55; and column 5, paragraph 68), a chamber body and chamber support wherein the chamber body is provided with a bearing surface via which chamber body is in a sealing connection with chamber support, so that a sample chamber is formed. Ehricht et al., disclose that the lid element, the intermediate element and the base element together form an optically translucent chamber having a chamber space (see figures 1-3).

For **claim 2**, Ehricht et al., discloses a device wherein the base element comprises an integrated heating-temperature sensor device. Ehricht et al., teaches (see column 3, paragraphs 31-32) that by means of the device, the PCR and the hybridization parallel to chip-bound nucleic acid are spatially combined in a temperature controllable and throughput controllable cell (chamber). Ehricht et al., also discloses heating and cooling elements which are placed on a chamber support together with temperature sensors and electrodes, which chamber support holding the chamber and being in a heat-conducting contact with same through the chamber bottom.

For **claim 3**, a device wherein the base element comprises monocrystalline silicon, Ehricht et al., discloses in column 4, paragraph 58 that the chip consists in a

known manner of an optically transparent support, the material of which, for example, can be silicon or glass.

For **claim 4**, a device wherein the lid element comprises Borofloat 33, Ehricht discloses (see column 4, paragraph 57) the chip can preferably be made of borofloat glasses.

For **claim 7**, a device wherein the recess defines a geometrical form of the chamber space. The examiner concludes that the geometrical form is meant to represent the arrangement of the library on the chip with respect to the recess. Ehricht et al., discloses (see abstract and column 4, paragraph 56) that the detection surfaces of the chip (in the form of spots) is mounted in the chamber body with a recess whose edge sealing holds an optically transparent chip consisting of individual spots on a detection surface in such a way that the detection surfaces in the form of spots are positioned opposite and facing the surface of the chamber support by edge of the chamber support. Finally, column 5, paragraph 69 (Figure 3) discloses the recess across which detection surfaces including spots of the chip is optically accessible.

For **claim 8**, wherein the chamber space may be filled free of air bubbles, Ehricht et al., discloses in column 6, paragraph 77 that contingent air bubbles can be discharged from capillary gap into gas reservoir of sample chamber.

For **claim 10**, a device wherein the chamber may be cooled, Ehricht et al, discloses in column 3, paragraph 31 that the device can be used for PCR, thus as a thermocycler which can ramp between various temperatures. Ehricht et al., also teaches that by means of the device, PCR and hybridization parallel to chip-bound

nucleic acid are spatially combined in a temperature-controllable and throughput controllable cell (chamber). In column 5, paragraph 63, Ehricht et al., also teaches that the heating elements can be preferably selected so that a fast heating and cooling of the liquid (in the capillary gap) is possible.

For **claim 12**, a device wherein the holding elements each comprise channels for cooling the chamber, Ehricht et al., discloses (see Fig 4 and column 5, paragraph 63) that the heating elements can be preferably selected so that a fast heating and cooling of the liquid in the capillary gap is possible. They further teach (Fig 4, column 5, paragraph 70) that the heating elements situated at the lower side of the (transparent) chamber support including conducting paths and connecting surfaces. Conducting paths are synonymous with channels.

For **claims 18-24**, a device which contains a protein, antibody, peptide, receptor/ligand, hormone, nucleic acid, DNA or RNA library, Ehricht et al., (see column 4, paragraph 57) disclose a chip that is preferentially functionalized by nucleic acid molecules, in particular by DNA or RNA molecules. However, the chips can likewise be functionalized by peptides and/or proteins such as, for example antibodies, receptors molecules, and pharmaceutically active peptides an/or hormones. Also, see the abstract where it teaches a device consists of a chamber body with a recess whose edge sealingly holds an optically transparent chip. Said chip holds nucleic acids (DNA or RNA) in individual spots on a detection surface.

Ehricht et al., teaches every element of claims 1-4, 7-8, 10, 12, 18-24; therefore these claims are rejected under 35 USC § 102e.

Claims 44, 45 are rejected under 35 USC 102(e) as being anticipated by Blackburn et al. (US 2006/0160205 A1. Date of Publication is 20 July 2006).

For **claims 44 and 45**, the device (for filling a second device as described in claim 1) wherein the body contains recesses for a filling unit, a ventilation unit and the second device, and wherein the recesses are arranged such that the sample chamber of the second device may be loaded and vented through puncturing of the intermediate element from its side. In Figs 1B and 1D, (see column 1, paragraph 10), it is shown an outlet port is positioned at the top and vents outside. Also shown in Figure 1C, the outlet port is located to the side of the chamber. Blackburn et al., also teaches in column 5, paragraph 62, the chips can include reaction chamber with inlet and outlet ports for the introduction and removal of reagents. In column 8, paragraph 91 and column 9, paragraph 91, Blackburn teaches the biochip or cartridge may have a vent. In column 8, paragraphs 88 and 89, Blackburn et al., discloses the inlet port may comprise a seal to prevent or reduce the evaporation of the sample or reagents from the reaction chamber, and the seal comprises a gasket, or valve through which a pipette or syringe can be pushed (thus puncturing the layer); also, a systems is used wherein the exit port vents to the inlet port, preferably above the point of loading. In column 8, paragraph 91, it is taught by Blackburn et al., that the biochip cartridge is designed to include one or more loading ports or valves that can be closed off or sealed after the sample is loaded and the biochip my have a vent. It is also shown, in column 3, paragraph 30, that the ventilation unit also comprises a second cannula. In this example, the use of a pipette tip can serve as a second cannula for loading a sample into a sample introduction

chamber (loading into a recess as in claim 45; see Figures 15A and 15C). Finally, in column 11, paragraph 131, Blackburn et al., disclose that the cartridge or biochip comprises a sealing and/or venting mechanism to prevent the cartridge from exploding or to prevent leakage.

Blackburn et al., teaches every element of claims 44 and 45; therefore, these claims are rejected under 35 USC § 102e.

Claims Rejections- 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3, 9, 10, 14-17, 44-45 are rejected under 35 USC 103 as being obvious over Lipshutz et al., (US Patent 5,856,174 (5 January, 1999).

For **claim 1**, a device for holding a substance library carrier having two holding elements that are fixable with each other and comprising a lid and base that are optically transparent in at least one area of detection and having a sealing intermediate element with an enclosed recess, Lipshutz et al., teaches in column 19, lines 20-29; discloses the use of an oligonucleotide array (substance library carrier) as the bottom

surface of a chamber. In column 27, lines 1-3; Lipshutz et al., disclose that the base unit my include a second surface which contacts the opposite surface of the device from the first surface, or one surface is "fixable" with a second surface. The device is made up of multiple chambers and at least one chamber will typically have as at least one surface, a transparent window for observation or scanning. Having "at least one transparent surface" implies there can be two surfaces that are transparent. Therefore, it would have been obvious to place the second transparent surface in the base, especially if the windows are to be used for viewing and scanning because the standard is to perform those two functions from opposite sides of the substance library. In column 18, lines 1-4; Lipshutz et al., teaches that the body of the device incorporates reaction chambers that are connected in series. In Column 19, lines 59-64, Lipshutz also discloses that the chambers included in the device of the invention have a centralized geometry having a central chamber for gathering and distribution of a fluid sample to a number of separate reaction/storage/analytical chambers arranged around, and fluidly connected to the central chamber.

For **claim 3**, a device wherein the base element comprises monocrystalline silicon, in column 14, lines 35-45, the reference teaches the body of the device is generally fabricated using one or more of a variety of methods and materials suitable for microfabrication techniques. For example, the body of the device may comprise a number of planar members that may individually be injection molded parts fabricated from a variety of polymeric materials, or may be silicon, glass, or the like. In the case of crystalline substrates like silica, glass, or silicon, methods for etching, milling, drilling,

etc., may be used to produce wells and depressions which makeup the various reaction chambers and fluid channels within the device.

For **claim 9**, a device wherein the chamber space is formed in the shape of a D, a new moon, or a sickle, Lipshutz, et al., teaches in column 14, lines 15-17; the body of the device may be embodied in any number of shapes depending upon the particular need. Thus, this anticipates a chamber space being formed in any shape.

For **claim 10**, the chamber may be cooled, Lipshutz et al., in column 2, line 55 teaches a chamber that can be temperature controlled. In column 19, lines 1-4; column 25, lines 6-8; column 27, 37-47, teach the device can be used for thermal cycling of the sample. One skilled in the art would know that this means rapid heating of cooling of the sample in a particular chamber to carry out an amplification reaction.

For **claim 14**, a device comprising a media connection for heating the chamber, and a media connection for cooling the chamber and a recess for receiving an injection apparatus, all of which are located on one side of the device, Lipshutz further discloses (see column 4, lines 40-45 and 55-64) chambers and components may also be included to provide reagents, buffers, sample manipulation, e.g., mixing, pumping, fluid direction (i.e. valves) heating and the like. It also discloses injecting the sample into the collection chamber through a sealable opening, e.g. an injection valve, or a septum. Alternatively, the device may be provided with a hypodermic needle integrated within the device and connected to the sample collection chamber.

For **claims 15-17**, a device with is attached to a connector and may be operated fully automatically through the connector and which is attached to a manual filling

station, Lipshutz et al, (see column 4, lines 16-45) discloses that the device will typically be one component of a larger diagnostic system that includes among other things a computer based interface for controlling the device. Furthermore, in Lipshutz, et al., (see column 5, lines 6-11) disclose that the reagents may generally be stored within the sample collection chamber of the device, or may be stored within a separately accessible chamber wherein the reagents may be added to or mixed. Finally, in column 5, lines 46-48, Lipshutz teach that the appropriate reagents may be incorporated within the [extraction] chamber or externally introduced.

For **claims 44, 45** the device previously described above, and a second device wherein the sample chamber of the second device may be loaded and vented through puncturing of the intermediate element from its side. Lipshutz et al, (see column 4, lines 56-64) discloses the sample may be directly injected into the collection chamber through a sealable opening, e.g., an injection valve, or a septum. The device may also be provided with a hypodermic needle integrated within the device and connected to the sample collection chamber.

Lipshutz et al., teaches every element of claims 1, 3, 9, 10, 14-17, 44-45; except for windows in both lid and base; however, Lipshutz's teachings of "at least one" window reasonably suggests the invention as claimed. Therefore, these claims are rejected as obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Garrison Owens whose telephone number is 571-270-

3060. The examiner can normally be reached on Monday - Thursday, 7:30AM - 5PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GAO

MARY MOSHER
SUPERVISORY PATENT EXAMINER

4-19-07